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PATENTS 8-12-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Benjamin Roderick Morrison, et al.	**Examiner:**	A.M. Falk
Serial No.:	09/732,520	**Art Unit:**	1632
Filed:	December 7, 2000	**Docket:**	14390

For: LONG-TERM CELL CULTURE COMPOSITIONS AND GENETICALLY MODIFIED ANIMALS DERIVED THEREFROM

Commissioner for Patents
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

I, John Roderick Morrison, hereby declare as follows:

1. I am one of the co-inventors named in the above-identified application ("the '520 application).

2. (Education) I hold a Bachelor of Science (B.S.) Degree in Biochemistry and a Doctorate Degree in Biochemistry.

3. (Employment history) I was employed as Senior Scientist at Monash Institute of Reproduction and Development. I am currently employed by CopyRat Pty Ltd.

4. I have worked in the field of Reproductive Biology since 1997.

5. I have authored 10 publications in the field of reproductive biology, cloning and the generation of genetically modified animals.

6. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

7. I have read the Final Action dated May 12, 2003, issued in respect of the '520 application. I have been asked to review and comment on issues raised by the Examiner in the Final Action.

8. The Examiner is of the opinion that the amendment filed February 19, 2003 (Paper No. 15) introduces new matter into the disclosure. Specifically, the Examiner is of the opinion that there has been no evidence submitted to verify that rats were used in the experiments of Example 12.

9. As one of the co-inventors named in the '520 application, I confirm that rats were used in the experiments of Example 12. Additional rat data in support of the findings outlined in Example 13 are enclosed herewith as Exhibit B, which describes the embryonic development of rat neural stem cells prepared as per Examples 1-5 of the '520 application and subject to nuclear transfer procedures outlined in Example 12 of the '520 application.

10. With respect to the disclosure of "transfected embryonic fibroblast" in the first column heading in the table on page 32 of the specification, the Examiner has maintained the objection that there is no guidance regarding what was used to transfect the fibroblasts. Specifically, the Examiner is of the opinion that that there is nothing in the specification to suggest that the transfected fibroblast in Example 13 carried the *lacZ* gene.

11. As one of the co-inventors named in the '520 application, I confirm that the *lacZ* gene was used in the transfection experiments referred to in Example 13.

12. In the Final Action, the Examiner states that no support is offered for the Applicant's assertion that procedures used in the rat can readily be used in other species. The Examiner further states that no support is offered for the Applicant's assertion that the

difficulties encountered in cloning various species could be overcome by routine experimentation.

13. I enclose herewith Exhibit C, which describes the formation of bovine embryos following nuclear transfer experiments on bovine neural stem cells.

14. The methodologies and results described in Exhibit C clearly illustrate that the method of isolating neural stem cells and the use of neural stem cells in nuclear transfer experiments in the bovine involve the same basic steps as those used in both the rat and mouse described in Exhibit B. For example, the nuclear transfer procedures described in all three species involve oocyte enucleation; introduction of the neural stem cell nucleus; activation of the oocyte to initiate embryonic development; and, culture *in vitro* to the morula/blastocyst stage. Whilst there is a requirement to adjust the techniques used in each species and differences in development outcomes are seen between species the basic approaches are the same. One skilled in the art in one species could, with some adjustments to protocol, practice the same art in another species, as was the case in Exhibits B and C.

15. In sum, it is my considered scientific opinion that the aforementioned results outlined in Exhibits B and C clearly demonstrate that the description and enablement of the technology in one mammalian species (rat) by the present invention, serves as validation of the approach in all other species.

16. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and

that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: _____ Dated: July 12, 2003